

**REMARKS**

The Examiner seems to possibly have rejected Claim 16 under 35 U.S.C. § 112, first paragraph, as failing to comply with the enablement requirement. In addition, the Examiner has rejected Claims 13-15, 21, and 23-26 under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 6,585,723 to Sumiya ("Sumiya"). The Examiner has also rejected Claims 17 and 18 under 35 U.S.C. § 103(a) as being unpatentable over Sumiya. In addition, the Examiner has rejected Claim 16 under 35 U.S.C. § 103(a) as being unpatentable over Sumiya in view of U.S. Patent Application Pub. No. 2004/0152987 to Haisch ("Haisch").

Claim 13 stands currently amended. Claims 1-12, 17, 19, 20, and 27-29 stand previously canceled. Claims 13-16, 18, and 21-26 are currently pending. The following remarks are considered by applicant to overcome each of the Examiner's outstanding rejections to current Claims 13-16, 18, and 21-26. An early Notice of Allowance is therefore requested.

**I. SUPPORT FOR AMENDMENT TO CLAIM 13**

Independent Claim 13 has been amended to state:

"An illuminating and irradiating unit for an ophthalmic instrument with a parallel beam path which is a portion of an illumination beam path that has boundaries which are parallel to each other, the illuminating and irradiating unit comprising:

"an illumination source which generates ~~an~~ the illumination beam;

"means for generating specific illumination patterns and/or profiles; ~~and~~

"means for coupling a complete one of the specific illumination patterns and/or profiles into the parallel beam path of the observation system of the ophthalmic instrument; and

"an objective lens arranged in the ophthalmic instrument which is arranged downstream from the means for coupling with respect to the illumination beam generated by the illumination source, such that (1) the parallel beam path is located upstream of the objective lens, and (2) a convergent beam path, which

is a portion of the illumination beam path that has boundaries which converge towards each other so as to create a focal point at an object, is located downstream of the objective lens;

“wherein optical filters, diaphragms, and/or optoelectronic light modulators with a control unit are used as the means for generating specific illumination patterns and/or profiles; and

“wherein a spectral range and a spatial range of the illumination beam is influenced by optical filters and/or diaphragms.”

Thus, the only amendments are (1) that an objective lens arranged in the ophthalmic instrument downstream from the means for coupling with respect to the illumination beam generated by the illumination source, and (2) that the parallel beam path (which is a portion of an illumination beam path that has boundaries which are parallel to each other) is located upstream of the objective lens and that the convergent beam path (which is a portion of the illumination beam path that has boundaries which converge towards each other so as to create a focal point at an object) is located downstream of the objective lens.

An optical microscope with an objective, as commonly known in the art, inherently has a parallel beam path (which is a portion of an illumination beam path that has boundaries which are parallel to each other) located upstream of the objective lens, and has a convergent beam path (which is a portion of the illumination beam path that has boundaries which converge towards each other so as to create a focal point at an object) is located downstream of the objective lens and converges at a focal point on an object. As such, no explicit description of this attribute of an objective need be included in the current Application, as it is an inherent property of an objective commonly known by any of ordinary skill in the art. Thus, there is support portion (2) of the amendment to Claim 13 (described above), since the device described current Application includes an objective. See Application, objective 9 (discussed in specification and shown in drawings).

In addition, as seen in Fig. 1 of the Application as filed, the objective 9 is located downstream of the illumination source 1, with the objective being located between the illumination source and the patient's eye 8 (i.e., the object). Thus, the device shown in Fig. 1 inherently has a convergent beam path portion located downstream of the objective 9

(i.e., between the objective 9 and the patients eye 8), and a parallel beam path portion located upstream of the objective 9. As such, the specification and drawings of the current Application provide ample support for portion (1) of the amendment to Claim 13 (described above).

Accordingly, all of the amendments to Claim 13 are either supported by the explicit disclosure of the current application, or by the inherent properties of the specific disclosure of the current Application as commonly known to those of ordinary skill in the art.

## **II. SUMMARY OF RELEVANT LAW**

A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference. The determination of obviousness rests on whether the claimed invention as a whole would have been obvious to a person of ordinary skill in the art at the time the invention was made. In determining obviousness, four factors should be weighed: (1) the scope and content of the prior art, (2) the differences between the art and the claims at issue, (3) the level of ordinary skill in the art, and (4) whatever objective evidence may be present. Obviousness may not be established using hindsight or in view of the teachings or suggestions of the inventor. The Examiner carries the burden under 35 U.S.C. § 103 to establish a prima facie case of obviousness and must show that the references relied on teach or suggest all of the limitations of the claims.

## **III. REJECTION OF CLAIM 16 UNDER 35 U.S.C. § 112, FIRST PARAGRAPH**

On page 2 of the current Office Action, the Examiner seems to reject Claim 16 under 35 U.S.C. § 112, first paragraph, as failing to comply with the enablement requirement. This rejection is respectfully traversed and believed overcome in view of the following discussion.

As a preliminary matter, Applicants note that no formal rejection under 35 U.S.C. § 112, first paragraph, has been made in the current Office Action. Accordingly, should Examiner wish to maintain any such rejection in a future Office Action, Applicants

respectfully assert that Examiner **must** provide a formal rejection of Claim 16 so that the record is clear.

In addition, any rejection of Claim 16 under 35 U.S.C. § 112, first paragraph, as failing to comply with the enablement requirement cannot be sustained.

As previously explained, the Specification clearly explains how an illuminating and irradiating unit for a slit lamp uses an illumination source 1 which is a narrow-band light in the **short-wavelength** range **around 365 nm**. Specification, ¶¶ [0017]-[0021]. The Specification also explains how other applications (e.g., photodynamic therapy (“PDT”)) use narrow-band, **long-wavelength** light, preferably around **690 nm**, which is emitted by the illumination source 1. Specification, ¶ [0022]. As such, having an illumination source which generates narrow-band light around 365 nm is **fully enabled** by the Specification.

On page 2 of the current Office Action, Examiner argues that it is unclear how light in the UV spectra is used to observe a patient’s eye. AS such, Examiner appears to be arguing regarding the utility of the claim. However, this has nothing to do with whether or no the specification contains sufficient disclosure to enable one of ordinary skill in the art to construct the device claimed. As discussed above, based on the disclosure of the current Application, one of ordinary skill in the art would clearly know how to provide an illumination source which generates narrow-band light in the short-wavelength range of around 365 nm, as stated in Claim 16. In fact, the current Application even explicitly states that the objective 9, which is arranged in the observation beam path, is preferably corrected in the UV and/or VIS range of light.

Accordingly, Applicants respectfully assert that Claim 16 is fully enabled. Therefore, Applicants respectfully assert the Examiner could not maintain a rejection of Claim 16 under 35 U.S.C. § 112, first paragraph, as failing to comply with the enablement requirement.

IV. REJECTION OF CLAIMS 13-15, 21, AND 23-26 UNDER 35 U.S.C. § 102(B)  
BASED ON SUMIYA

On page 5 of the current Office Action, the Examiner rejects Claims 13-15, 21, and 23-26 as being anticipated by Sumiya. These rejections are respectfully traversed and believed overcome in view of the following discussion.

Claim 13 states, in part:

“An illuminating and irradiating unit for an ophthalmic instrument with a **parallel beam path which is a portion of an illumination beam path that has boundaries which are parallel to each other**, the illuminating and irradiating unit comprising:

“an illumination source which generates the illumination beam;

“means for generating **specific illumination patterns and/or profiles**;

“means for **coupling a complete one** of the specific illumination patterns and/or profiles **into the parallel beam path** of the observation system of the ophthalmic instrument; and

“an **objective lens** arranged in the ophthalmic instrument which is **arranged downstream from the means for coupling with respect to the illumination beam generated by the illumination source**, such that **(1) the parallel beam path is located upstream** of the objective lens, and **(2) a convergent beam path**, which is a portion of the illumination beam path that has boundaries which converge towards each other so as to create a focal point at an object, **is located downstream** of the objective lens;

“wherein optical filters, diaphragms, and/or optoelectronic light modulators with a control unit **are used as the means for generating specific illumination patterns and/or profiles**; and

“wherein a **spectral range** and a **spatial range** of the illumination beam is **influenced by optical filters and/or diaphragms**.” (emphasis added).

**A. Specific Illumination Patterns and/or Profiles****(1) *Prior Arguments***

As set forth above, Claim 13 requires that there is a means for **generating specific illumination patterns and/or profiles**, and that there is a means for **coupling a complete one** of the specific illumination patterns and/or profiles into a parallel beam path of the observation system of the ophthalmic instrument. Sumiya fails to disclose these elements of Claim 13.

In particular, Sumiya is directed to a device for corneal surgery for ablating a portion of the cornea of a patient's eye to correct refraction defects of the eye or to remove a lesion from an eye. Such ablation of the cornea of a patient's eye is carried out, for example, with the aim of changing the refractive power for correcting ametropia such as myopia, hypermetropia, astigmatism, and the like or to remove an affected area of the cornea such as opacity.

For this purpose, Sumiya's arrangement comprises an irradiation unit which directs a laser beam to an area on the cornea of a patient's eye. But the laser beam is **not** focused on this area so as to **generate specific illumination patterns and/or profiles**.

Furthermore, Sumiya's arrangement comprises a cornea shape measuring unit for measuring the three-dimensional shape of the cornea which has an optical measurement light projection system for **projecting measurement light onto the cornea**. The measurement light reflected by the cornea is received and evaluated by an optical photodetector.

In order to calculate the three-dimensional shape of the cornea, the cornea is scanned in the X-Y directions. For this purpose, the **projection spot of measurement light** is displaced on the cornea by a scan unit in X-Y directions. Accordingly, **no specific illumination patterns and/or profiles are generated** by the optical measurement light projection system either.

Moreover, Sumiya's solution does **not** describe an illumination and irradiation unit for ophthalmic instruments, **but rather** describes a device for corneal surgery for scanning the cornea and for ablating portions of the cornea of the patient's eye.

In addition, Sumiya's solution does **not** contain means for generating specific illumination patterns and/or profiles. On the contrary, an **individual laser spot is focused**

on the cornea (to be scanned or ablated) in Sumiya. The cornea is scanned correspondingly by means of a scanning unit. While *ultimately* a pattern is generated by the scanning unit, this takes place *gradually* by scanning. In Claim 13, however, **complete** illumination patterns and/or profiles are generated and imaged on the eye.

Also, no illumination patterns and/or profiles within the meaning of Claim 13 are generated in Sumiya. More specifically, in Sumiya a “pattern” is generated by the scanning movement of a laser spot. In Claim 13 however, a one-time generation of a **complete illumination pattern and/or profile** which is imaged on the eye **simultaneously** is carried out. This **cannot** be accomplished by the scanning unit of Sumiya.

In fact, Sumiya states that the control unit 40 calculates the three-dimensional cornea shape based on detection signals of the **spot** of the infrared laser beam of the measurement light projection system. Sumiya, Col. 7, Ln. 63 – Col. 8, Ln. 8. Irradiation **spots** can **hardly be** called specific illumination **patterns or profiles**.

Therefore, Sumiya’s solution does not contain any means for generating and coupling **complete** specific illumination patterns and/or profiles. The optical elements which the Examiner identifies as such means are **not suited** for generating illumination patterns and/or profiles, or for coupling **a complete one** of the specific illumination patterns and/or profiles into a parallel beam path of the observation system of the ophthalmic instrument.

Put another way, the device disclosed by Sumiya relates to the field of corneal surgery (in particular the removal of part of the cornea of an eye) with the aim of correcting a refractive error of the eye. The apparatus includes an illumination unit to which a laser beam focused to a designated area on a cornea of the eye of a patient. The laser beam forms a spot which is focused on the cornea (for removing a portion of the cornea). Thus, a special illumination pattern or profile is **not** required.

The only so-called profiles or patterns that Sumiya can be interpreted as generating are a number of successively generated and positioned isolated spots, which are generated with the removal of successive parts of the cornea.

Background information about this topic can be found for example, under the keyword “Corneal Surgery” on the Internet to a sufficient extent.

Thus, the position of the Examiner that the laser spot of Sumiya generates **complete** illumination patterns and profiles is **incorrect**. Conversely, solution of Claim 13 is able to create individual spots or groups of spots and focused on the eye. In contrast, the laser spot of Sumiya is hardly suitable for a **complete** illumination pattern or profile, because the laser of Sumiya is focused on one point.

Accordingly, to further clarify the difference between the invention of Claim 13 and the disclosure of Sumiya, Claim 13 has been amended (as set forth above) to require that a **spectral range** and a **spatial range** of the illumination beam is **influenced by optical filters and/or diaphragms**. This amendment more precisely defines the lighting patterns or profiles, and is supported by paragraph [0017] the current Application, which states:

“... The spectral and spatial range of the illumination beam can be influenced by optical filters 4 and/or diaphragms 5. ...”

While spectral interference of a laser **spot** may well still take place, this will **not** be possible in geographical terms for a **spatial** range of the illumination beam of Sumiya.

In sum, as stated above, Sumiya concerns a device for corneal surgery for removing a portion of the cornea of the eye of a patient, for example to correct a refractive error of the eye. For this purpose, the device of Sumiya includes a lighting unit, a measurement beam focused on the cornea of the eye of a patient. By means of a scanning unit, the cornea in the x and y directions is sampled to determining the direction of its shape. Sumiya realizes a successive scanning of the cornea with a laser spot.

Following the same successive principle, treatment is then carried out (i.e., the local ablation of the cornea). For such treatments, the use of pulsed excimer laser is enforced in the known prior art. By Sumiya, such a laser will be used. See Sumiya, Col. 8, Ln. 43 - Col. 9, Ln. 4.

These laser spots neither require nor desire special illumination patterns and/or profiles. To achieve an accurate determination of the corneal shape, as well as targeted removal of parts of the cornea, the individual spots should be of equal size and energy density, and accurately focused.



Thus, it is clear from amended Claim 13 that Sumiya fails to disclose imaging a complete illumination pattern or profile on an eye, as set forth in Claim 13.

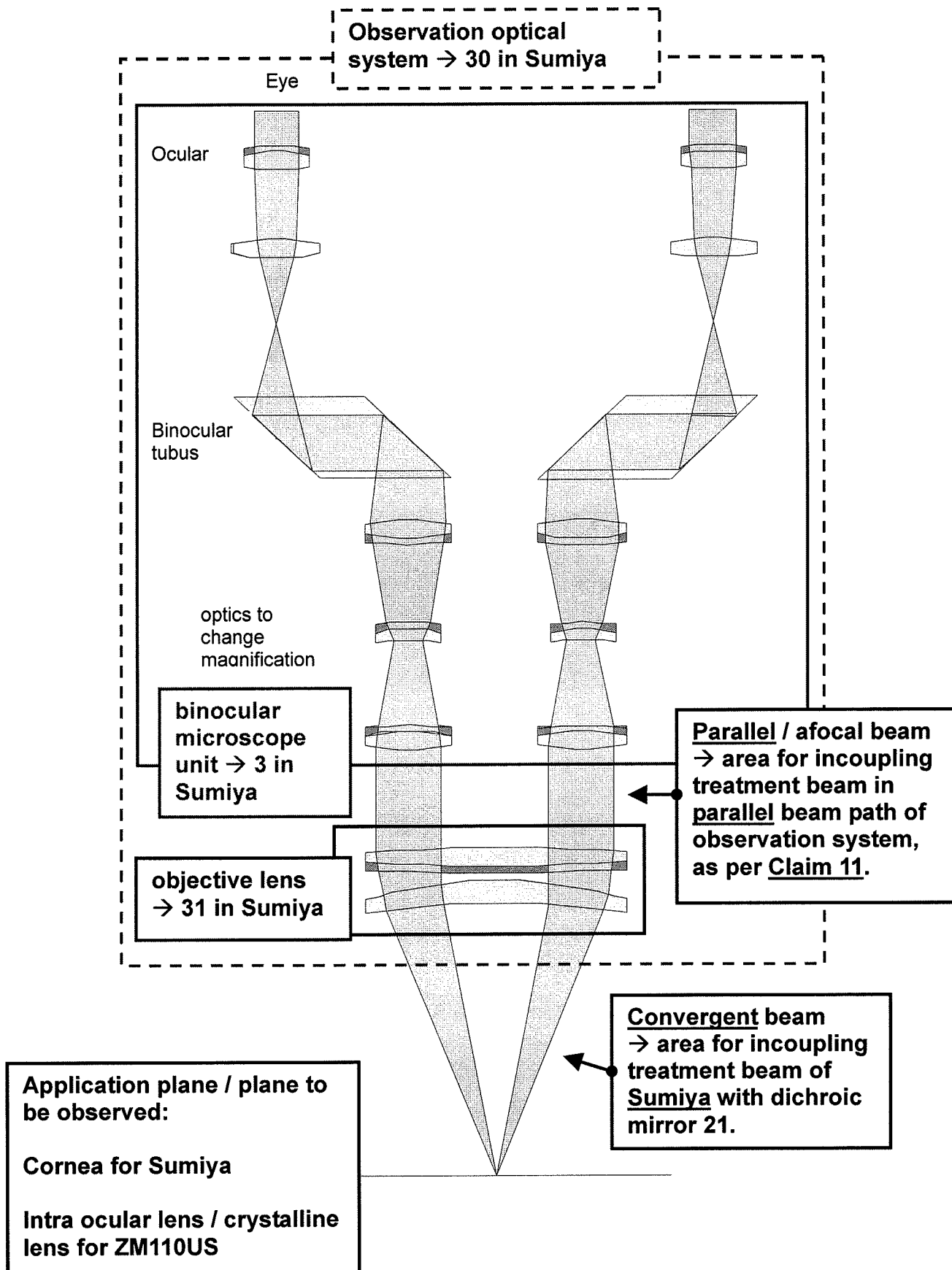
**B. Coupling the Patterns and/or Profiles into the Parallel Beam Path**

***(1) Prior Arguments***

Further, the light from the illumination source is **not** coupled into the **parallel beam path of the observation system** of the ophthalmic instrument in Sumiya. On the **contrary**, the measurement beam from the laser source 11 and the therapy beam from the excimer laser 26 are reflected into the beam path **focused on the cornea** by the dichroic mirror 21. The only parallel beam paths in Sumiya are between the lenses 31 and 36 in the observation beam path and between the lenses 15 and 18 in the illumination beam path.

To clarify, Sumiya does teach that the laser beam from beam source 11 is coupled into the observation beam path of the optical system 30. However, the coupling does **not** occur in the **parallel beam of the observation system**, as required by Claim 13.

The below annotated figure (which refers to the claimed position of coupling in Claim 13, and the position of coupling in Fig 2 of Sumiya between the dichroic mirror 21 and the eye E) illustrates the difference described above:



The sketch above shows the different points for coupling of the beam (i.e., location of coupling for Claim 13, and location for coupling of Sumiya).

In Sumiya, lens 31 is the objective lens (the last lens) of the stereomicroscope. This is also supported by the fact that the “photographic lens” 36 must here represent the infinity optical path for “finally” on the CCD 39. In addition, so that the laser spot can be focused on the cornea (the goal of Sumiya), the dichroic mirror 21 requires that in the convergent beam path shown above.

In the solution of Claim 13, the parallel beam path was chosen for the location of coupling, since the use of a beam splitter is best not to produce aberrations. It creates only a beam displacement by a beam splitter plate.

As such, the claimed location of coupling (i.e., coupling into the **parallel beam path of the observation system** of the ophthalmic instrument) is not disclosed by the coupling of Sumiya (i.e., coupling into a **convergent** beam path of the observation system). Thus, Sumiya fails to disclose a means for **coupling a complete one** of the specific illumination patterns and/or profiles into the **parallel beam path of the observation system** of the ophthalmic instrument, as required by Claim 13.

### ***(2) Amendments Clarifying “Parallel Beam Path”***

Independent Claim 13 has been amended to clarify exactly what is meant by a “parallel beam path”. More specifically, both a parallel beam path and a convergent beam path have been defined with respect to an objective. In addition, the location of the objective itself has also been described in amended Claim 13. Applicants respectfully assert that these clarifications to Claim 13 adequately distinguish the claims over the current cited art.

### **C. June 29, 2010 Interview With Examiner**

A telephonic interview with Examiner was held on June 29, 2010. During that interview, the above amendments to Claim 13 were discussed in relation to the current rejections. Examiner admitted that the amendments to Claim 13 overcome the current rejection of Claim 13. **Accordingly, Examiner indicated that the current rejections of the claims would withdrawn in any future Office Action.**

**D. Conclusion**

For the reasons set forth above, Applicant respectfully asserts that Examiner has failed to establish a prima facie case of anticipation of independent Claim 13, and corresponding Claims 14, 15, 21, and 23-26 because they are each ultimately dependent from Claim 13. Therefore, Applicant respectfully requests that Examiner remove the rejection of Claims 13-15 and 20-26 under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 6,585,723 to Sumiya.

**V. REJECTION OF CLAIMS 18 AND 22 UNDER 35 U.S.C. § 103(A) BASED ON SUMIYA**

On page 6 of the current Office Action, the Examiner rejects Claims 18 and 22 as being unpatentable over Sumiya. These rejections are respectfully traversed and believed overcome in view of the following discussion.

Claims 18 and 22 are dependent from independent Claim 13. As Claim 13 is allowable, so must be Claims 18 and 22. Accordingly, Applicants respectfully assert that Examiner has failed to establish a prima facie case of obviousness of Claims 18 and 22. Therefore, Applicant respectfully requests that Examiner remove the rejection of Claims 18 and 22 under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 6,585,723 to Sumiya.

**VI. REJECTION OF CLAIM 16 UNDER 35 U.S.C. § 103(A) BASED ON SUMIYA IN VIEW OF HAISCH**

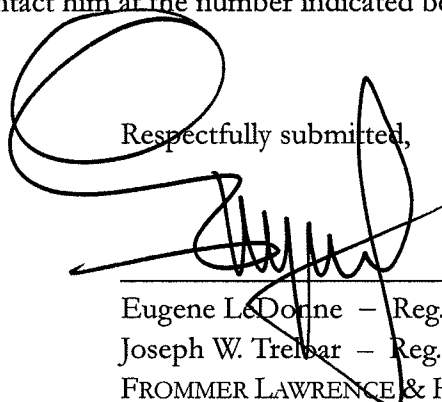
On page 7 of the current Office Action, the Examiner rejects Claim 16 as being unpatentable over Sumiya in view of Haisch. This rejection is respectfully traversed and believed overcome in view of the following discussion.

Claim 16 is ultimately depend from independent Claim 13. As Claim 13 is allowable, so must be Claim 16. Accordingly, Applicants respectfully assert that Examiner has failed to establish a prima facie case of obviousness of Claim 16. Therefore, Applicant respectfully requests that Examiner remove the rejection of Claim 16 under 35 U.S.C.

§ 103(a) as being unpatentable over U.S. Patent No. 6,585,723 to Sumiya in view of U.S. Patent Application Pub. No. 2004/0152987 to Haisch.

Based upon the above remarks, Applicant respectfully requests reconsideration of this application and its early allowance. Should the Examiner feel that a telephone conference with Applicants' attorney would expedite the prosecution of this application, the Examiner is urged to contact him at the number indicated below.

Respectfully submitted,



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